

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC. and	)	
BAYER HEALTHCARE LLC,	)	
	)	
Plaintiffs,	)	C. A. No. 05-349-GMS
	)	
v.	)	JURY TRIAL DEMANDED
	)	
BAXTER INTERNATIONAL INC. and	)	<b>PUBLIC VERSION</b>
BAXTER HEALTHCARE CORPORATION,	)	
	)	
Defendants.	)	
	)	
	)	
<hr/>		
BAXTER HEALTHCARE CORPORATION,	)	
	)	
Counterclaimant,	)	
	)	
v.	)	
	)	
TALECRIS BIOTHERAPEUTICS, INC. and	)	
BAYER HEALTHCARE LLC,	)	
	)	
Counterdefendants.	)	

**OPENING BRIEF OF DEFENDANT BAXTER INTERNATIONAL INC.  
AND DEFENDANT/COUNTERCLAIMANT BAXTER HEALTHCARE  
CORPORATION IN SUPPORT OF THEIR MOTION FOR LEAVE TO FILE  
AMENDED ANSWER AND COUNTERCLAIM**

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## TABLE OF CONTENTS

	<u>Page</u>
I. Introduction.....	1
A. Statement and Nature of the Proceedings .....	1
II. Statement of Compliance with Local Rule 7.1.1 .....	2
III. Summary of Argument .....	2
IV. Statement of Facts.....	3
A. Prosecution of the Alonso Patent Application .....	3
B. Baxter's Proposed Amendment .....	5
C. Relevant Procedural Facts.....	5
V. Argument .....	7
A. Standards Applicable to Motion for Leave to Amend .....	7
B. There Is No Undue Delay, Undue Prejudice or Other Reason to Deny Baxter Leave To Amend .....	9
1. The Inequitable Conduct Claim Is Meritorious .....	9
2. Plaintiffs Will Suffer No Prejudice.....	12
3. Other Factors Favor Granting Baxter Leave To Amend .....	13
VI. Conclusion .....	13

## TABLE OF AUTHORITIES

	<u>Page</u>
<b>Cases</b>	
<i>Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.</i> , 989 F. Supp. 1237 (N.D. Cal. 1997).....	8
<i>Burlington Indus., Inc. v. Dayco Corp.</i> , 849 F.2d 1418 (Fed. Cir. 1988).....	8
<i>Cornell &amp; Co. v. Occupational Safety &amp; Health Review Comm'n</i> , 573 F.2d 820, 823 (3d Cir. 1978).....	8
<i>Dole Fresh Fruit Co. v. Delaware Cold Storage, Inc.</i> , 961 F. Supp. 676 (D. Del. 1997).....	7
<i>Douglas Press, Inc. v. Tabco, Inc.</i> , No. 00 C 7338, 2004 WL 1144054 (N.D. Ill. May 17, 2004) .....	8
<i>Enzo Life Sciences, Inc. v. Digene Corp.</i> , 270 F. Supp. 2d 484 (D. Del. 2003).....	8
<i>FilmTec Corp. v. Hydranautics</i> , 67 F.3d 931 (Fed. Cir. 1995).....	7
<i>Foman v. Davis</i> , 371 U.S. 178 (1962).....	7
<i>Lorenz v. CSX Corp.</i> , 1 F.3d 1406 (3d Cir. 1993) .....	7
<i>MercExchange, L.L.C. v. eBay, Inc.</i> , 271 F. Supp. 2d 784 (E.D. Va. 2002) .....	8
<i>Rhône-Poulenc Agro S.A. v. Monsanto Co.</i> , 73 F. Supp. 2d 537 (M.D.N.C. 1999) .....	8
<i>Shane v. Fauver</i> , 213 F.3d 113 (3d Cir. 2000).....	7
<b>Statutes</b>	
35 U.S.C. § 102(b).....	11
<b>Rules</b>	
Fed. R. Civ. Proc. 15.....	1, 2, 7
Fed. R. Civ. Proc. 9(b).....	2, 8

## **I. Introduction**

The “anomalous results” claimed by Bayer, which persuaded the Board of Patent Appeals and Interferences to issue the patent-in-suit here, were not valid. Rather, material, contradictory data from the experiments of inventor William R. Alonso (“Alonso”) was withheld from the United States Patent and Trademark Office (“PTO”). Had this significant data been disclosed U.S. Patent No. 6,686,191 (the “Alonso Patent” or “’191 Patent”) almost surely would not have issued.

Defendants learned this startling information during discovery in this case. This discovery occurred after the Court’s deadline for amending pleadings. Consequently, defendants Baxter International and Baxter Healthcare Corporation (hereafter, “Baxter”) seek leave to file an Amended Answer and Counterclaim that includes allegations of inequitable conduct. Baxter’s motion comports with the requirements of Federal Rule of Civil Procedure 15 because Baxter has not unduly delayed seeking leave to file, plaintiffs will suffer no legal prejudice if the motion is granted, and the affirmative defense and counterclaim to be added have merit.

### **A. Statement and Nature of the Proceedings**

This is a patent infringement action filed on June 1, 2005 by Talecris Biotherapeutics, Inc. (“Talecris”), the licensee of the Alonso Patent. Talecris amended its complaint by stipulation on May 5, 2006 to add a claim for damages and also to add Bayer Healthcare LLC (“Bayer”) as a plaintiff. Baxter answered the Complaint and Amended Complaint on August 31, 2005 and May 30, 2006 respectively. In its Answer and Amended Answer, Baxter included four affirmative defenses for failure to state a claim, non-infringement, patent invalidity, and estoppel. Baxter also counterclaimed for a declaratory judgment that it does not infringe the ‘191 Patent and that the ‘191 Patent is invalid. Baxter did not assert inequitable conduct because discovery

had not yet begun in earnest; Baxter would not make such a serious allegation unless and until it had sufficient evidence to warrant making such a claim in good faith. It now does.

## **II. Statement of Compliance with Local Rule 7.1.1**

Baxter's counsel made a reasonable effort to reach agreement with plaintiffs' counsel on the matters set forth in this motion, but agreement was not reached. Declaration of Brian T. Clarke in Support of Baxter's Motion for Leave to Amend Its Answer ("Clarke Decl.") at ¶ 2.

## **III. Summary of Argument**

1. Rule 15 of the Federal Rules of Civil Procedure<sup>1</sup> provides that leave to amend a party's pleadings should be freely given. Leave to add Baxter's allegations of inequitable conduct should be granted because there has been no undue delay, bad faith, dilatory motive, or undue prejudice to the opposing party. Nor would amendment be futile.

2. The Court should allow Baxter to allege inequitable conduct in the prosecution of the '191 Patent as an affirmative defense and counterclaim because:

a. Inequitable conduct is a well-established defense to patent infringement, and the facts support such a defense in this case.

b. Baxter has not unduly delayed seeking leave to amend. Rule 9(b) requires that inequitable conduct be pled with particularity. As a result, abundant case law provides that a defendant should pursue discovery to investigate the relevant facts before adding the defense. Consequently, courts frequently allow the addition of inequitable conduct allegations after the deadline to amend pleadings has passed. Much of the evidence on which Baxter bases its inequitable conduct defense and counterclaim has only recently come to light.

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<sup>1</sup> Hereafter, all references to the Federal Rules of Civil Procedure will be to "Rule \_\_\_\_."

c. Plaintiffs will not be prejudiced by amendment at this stage of the case. Talecris and Bayer are in possession of all of the relevant facts. Baxter's inequitable conduct defense is based on the conduct of the inventor of the Alonso Patent (a Talecris employee) and the attorneys who prosecuted the Alonso Patent, all of whom Plaintiffs' counsel represented in deposition. Clarke Decl. at ¶ 3. Because the relevant documents and witnesses are all within Plaintiffs' control, they require no further discovery to defend against the inequitable conduct allegation. Additionally, Baxter also will require no new discovery<sup>2</sup>, and by its motion Baxter simply seeks to conform the pleadings with the evidence it has obtained during discovery.

#### **IV. Statement of Facts**

##### **A. Prosecution of the Alonso Patent Application**

The Alonso Patent claims a method for preparing virally-inactivated, intravenously-administrable, immunoglobulin solutions. The method combines solvent-detergent treatment to inactivate viruses with an "incubation" step to reduce anticomplement activity. Clarke Decl., Ex. 1, p. 8, Claim 1. It was well known in the art that viral activity and anticomplement activity both should be minimized in any intravenous immunoglobulin ("IVIG") therapy. Clarke Decl., Ex. 2, pp. 8-9. Moreover, it was known that solvent-detergent treatment inactivated viruses and that incubation under specified conditions reduced anticomplement activity ("ACA"). *Ibid*, pp. 4-9. For that reason the PTO examiner considered Alonso's claims obvious, and refused to issue a patent. Clarke Decl., Ex. 3, pp. 3-4.

Alonso, a scientist at Bayer, and Bayer's attorneys, appealed the examiner's Final Rejection to the Board of Patent Appeals and Interferences (the "Board"). Bayer's sole

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<sup>2</sup> The parties are in the process of completing responses and productions to outstanding discovery requests, but Baxter does not require any new (previously unrequested) discovery.

argument for patentability was that Alonso had discovered an unknown and surprising thing: after solvent-detergent treatment to inactivate viruses the ACA level in the IVIG solution increased to unacceptable levels thereby necessitating an incubation step to reduce ACA again. Specifically, Bayer's lawyer argued:

"The increase in ACA caused by the TNBP step in step (a) was unexpected....  
The claimed invention requires that the conditions pH, temperature and ionic strength of step (b) be selected to reduce the ACA to a level acceptable for intravenous administration."

Clarke Decl., Ex. 4, p. 4 (emphasis in original).

Based on the assertion that an incubation step was "required" to reduce ACA to a level acceptable for intravenous administration, Bayer sought allowance of the patent. That assertion, however, was not true. Dr. Alonso's experimental data refuting this assertion, although in the possession of Bayer, was never disclosed.

Relying on the representation of Bayer's counsel, the Board reversed the Examiner and issued the Alonso Patent:

"We observe that it is not in dispute that appellant's process combines two relatively well-known steps to accomplish known functions.

\* \* \*

However, the claimed subject matter requires that the inactivation step result in an increase in ACA levels, and a reduction in that claimed increase by the incubation step to a point where the solution is suitable for intravenous use."

Clarke Decl., Ex. 5, p. 5 (emphasis added in original).

Continuing, the Board made explicit its reliance on Bayer's test data:

"The appellants state that they treated the solvent detergent virally inactivated ISG obtained by way of the Neurath process with the Tenold ACA lowering procedure *and that the resulting product did not have an initially acceptable ACA level.*

\* \* \*

Once appellants did what the prior art would reasonably appear to suggest doing, they found they did not obtain the expected results. It was only after obtaining the *anomalous results* did they understand the problem and discover its solution.”

*Id.*, pp. 9, 11 (emphasis added).

Because of the allegedly "anomalous" results the patent was allowed. [REDACTED]

[REDACTED] **REDACTED** [REDACTED]

[REDACTED] The “anomalous result” was only that, an anomaly itself. Consequently, there was no real “problem” and no “solution” invented by Dr. Alonso. While Bayer has always known this, Baxter only learned it through discovery conducted over the last few months.

**B. Baxter’s Proposed Amendment**

Because of this newly-discovered evidence, Baxter seeks leave to add one new affirmative defense and a related counterclaim. *See* Exhibit A, attached to Baxter’s accompanying Motion for Leave to File Amended Answer and Counterclaim. Baxter seeks to allege that the ‘191 Patent is unenforceable by virtue of inequitable conduct before the U.S. Patent and Trademark Office. The defense is based on the intentional failure to disclose information material to the patentability of the ‘191 Patent to the Patent Office. Baxter also seeks to assert a counterclaim requesting a declaratory judgment that the Alonso Patent is unenforceable, based on the same allegations.

**C. Relevant Procedural Facts**

Discovery began in this action in April, 2006. Talecris and Bayer did not begin producing responsive documents until May 19, 2006, and this was just the beginning of their



rolling production.<sup>3</sup> In total, plaintiffs disclosed approximately 127,000 pages of information, however Baxter could not complete its investigation, including the deposition of the inventor, until late September and early October.

Baxter has diligently analyzed the documents produced by plaintiffs.

REDACTED

Moreover, through

Dr. Alonso's deposition and other depositions taken in late September and early October, Baxter learned that Dr. Alonso was well aware of Bayer's Gamimune N process/product, which is highly material to the invalidity of Claim 23, yet Bayer did not disclose this prior art to the PTO. Additionally, at least Bayer's patent attorneys—if not Dr. Alonso himself—were aware of two references written by other Bayer employees that were material to the claims being prosecuted, but these references also were not disclosed to the PTO.

Based on the documents obtained from plaintiffs and Dr. Alonso's testimony in late September and early October, Baxter determined that there were sufficient facts to plead inequitable conduct. Baxter sought from Plaintiffs' counsel a stipulation to file this amended pleading. Talecris and Bayer refused to so agree, thereby necessitating this motion.

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<sup>3</sup> Plaintiffs produced additional documents to Baxter on May 19, June 8, June 16, June 21, June 27, July 10, July 24, July 26, August 11, August 12, August 17, August 30, September 13, September 15, September 29 and October 4 of 2006.

## V. Argument

### A. Standards Applicable to Motion for Leave to Amend

Under Rule 15, leave to amend a pleading “shall be freely given when justice so requires.” The policy to freely allow amendment assures that cases will be heard on their merits and avoids injustices that sometimes result from strict adherence to technical pleading requirements. *Foman v. Davis*, 371 U.S. 178, 181-82 (1962).

Rule 15 reflects the limited role of federal pleadings. The purpose of pleadings is to provide the parties with fair notice of the general nature of the pleader’s defense. As long as such notice has been provided, the pleading should not limit a party’s claims or defenses. *Id.* at 182 (“If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits.”). In ruling on a motion for leave to amend, “a court must be guided by the underlying purpose of Rule 15 – to facilitate decision on the merits rather than on the pleadings or technicalities,” *FilmTec Corp. v. Hydranautics*, 67 F.3d 931, 935 (Fed. Cir. 1995), and should follow a “liberal policy of granting leave to amend . . .” *Dole Fresh Fruit Co. v. Delaware Cold Storage, Inc.*, 961 F. Supp. 676, 686 (D. Del. 1997).

As a result of this liberal standard, it has been found to be an abuse of discretion to deny leave to amend without justification. *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000). “[T]he trial court may not deny leave to amend ‘[i]n the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment.’” *Dole Fresh Fruit Co.*, 961 F. Supp. at 686 (quoting *Foman v. Davis*, 371 U.S. at 182). “[P]rejudice to the non-moving party is the touchstone for the denial of an amendment.” *Lorenz v. CSX Corp.*, 1 F.3d 1406,

1414 (3d Cir. 1993) (*quoting Cornell & Co. v. Occupational Safety & Health Review Comm'n*, 573 F.2d 820, 823 (3d Cir. 1978)).

The deadline to file amended pleadings in this case was May 5, 2006. At that stage of this case, however, discovery was just beginning. Indeed, Talecris' first production of documents was May 19, 2006. Consequently, on May 5, 2006, Baxter did not yet have sufficient facts in its possession to add an inequitable conduct counterclaim in good faith. Prematurely alleging inequitable conduct without the underlying facts to support the allegations has been characterized as a "plague." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("[H]abit of charging inequitable conduct in almost every major patent case has become an absolute plague. . . . A patent litigant should be made to feel, therefore, that an unsupported charge of 'inequitable conduct in the Patent Office' is a negative contribution to the rightful administration of justice."). Acting responsibly, Baxter has waited until it has probative evidence in hand before seeking to assert these claims.

Rule 9(b) demands pleading with particularity an allegation of inequitable conduct, which requires a thorough investigation of facts. Indeed, many courts have held that a defendant in a patent case should be permitted—or even required—to pursue relevant discovery before pleading inequitable conduct. *E.g., Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 487-90 (D. Del. 2003) (Because of the particularity requirement for inequitable conduct allegations "[defendant] was prudent and possibly required to confirm the factual allegations through discovery"); *Douglas Press, Inc. v. Tabco, Inc.*, No. 00 C 7338, 2004 WL 1144054, \*1-\*2 (N.D. Ill. May 17, 2004) (Ex. A hereto) ("Allegations of inequitable conduct are serious and we cannot fault Tabco for waiting for further evidence before filing such an affirmative defense"); *MercExchange, L.L.C. v. eBay, Inc.*, 271 F. Supp. 2d 784, 786-89 (E.D. Va. 2002) (granting

leave to amend to add inequitable conduct defense, citing cases also permitting amendment based in part on the particularity pleading requirement for inequitable conduct); *Rhône-Poulenc Agro S.A., v. Monsanto Co.*, 73 F. Supp. 2d 537, 539 (M.D.N.C. 1999) (holding it appropriate for defendant to wait to take depositions in light of pleading-with-particularity requirement for inequitable conduct); *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 989 F. Supp. 1237, 1247 (N.D. Cal. 1997) (“because the legal theory . . . requir[es] pleading of fraud with particularity, SciMed was entitled to confirm factual allegations [through depositions] before amending to include the inequitable conduct defense.”).

**B. There Is No Undue Delay, Undue Prejudice or Other Reason to Deny Baxter Leave To Amend**

**1. The Inequitable Conduct Claim Is Meritorious**

The U.S. application that ultimately issued as the ‘191 Patent was filed on or about September 22, 1995, and the ‘191 Patent issued February 3, 2004.

**REDACTED**

In the specification for the ‘191 Patent and its file history, Bayer emphasized that the solvent-detergent treatment (step (a) in Claim 1) of an antibody solution “always” increased ACA levels and that the incubation step (step (b) in Claim 1) was critical to reduce ACA in the solutions to acceptable levels. *E.g.* Clarke Decl., Ex. 1, Col. 2:10-14, Col. 5:47-49; Ex. 6, p. 2 (solvent-detergent “resulted in a surprising but undesirable increase in ACA”), Ex. 7, p. 2 (solvent-detergent step causes increase of ACA). Dr. Alonso identified the significance of his invention as the ability to lower ACA of antibody solutions—the increase being caused by solvent-detergent treatment of the solution—to a level acceptable for intravenous administration. *E.g.* Clarke Decl., Ex. 1, Col. 7:20-24 (“[U]sing the prior art SD process for viral inactivation of

a solution containing ISG, subsequently formulated according to the Tenold '608 patent, yields a product which has high ACA and is unsuitable for intravenous administration.”); (“If there is no such increase [in ACA from step (a)], then step (b) of the invention, and the invention itself, is not needed.”). Clarke Decl., Ex. 4, p. 3.

However, the evidence now reveals that Bayer knew solvent-detergent treatment did not “always” increase ACA to an unacceptable level and, therefore, did not necessarily require an incubation step to reduce ACA.<sup>4</sup>

Clarke Decl., Ex. 8.

REDACTED

Bayer did not disclose to the United States Patent

Office this data that contradicted its assertions that solvent-detergent treatment of an antibody solution always increases ACA to an unacceptable level, (Clarke Decl., Ex. 1, Col. 2:10-14), the very hypothesis of the invention.

REDACTED

<sup>4</sup> During claim construction, the Court will have to determine whether the vague term “acceptable” is capable of a concrete meaning. The patent itself, however, provides that for a 5% solution of IVIG, the ACA level should be “less than about 45 CH<sub>50</sub> units/mL.” Clarke Decl., Ex. 1, Claim 3.



REDACTED

Notably, Bayer included data in the patent application that it did not disclose to the FDA when seeking authorization to sell its IVIG product in the United States.

REDACTED

However, Table 7 of the

'191 Patent includes data for sample A4, which has an ACA level nearly three times (122 CH<sub>50</sub> units/mL) the levels reported for samples A1-A3

REDACTED

But by including this outlier in the data in the patent application, Bayer skewed the average ACA of the samples in the patent application from acceptable to unacceptable, which average was used to demonstrate that solvent-detergent treatment always increased ACA.

In addition to withholding important experimental results, Bayer failed to disclose to the United States Patent Office two material references in the possession of it and/or its prosecuting attorneys: (1) U.S. Patent no. 5,256,771 ("the Tsay patent") and (2) Ng, *et al.*, Process-Scale Purification of Immunoglobulin M Concentrate, *Vox Sang.* 65:81-86 (1993). Both are 35 U.S.C. § 102(b) references, and both were owned by Bayer or authored by one of its employees. Additionally, Bayer was aware of its own Gamimmune N product and the process for making it.

This product is highly material to the patentability of Claim 23, at a minimum, as it anticipates Claim 23. Gamimune N is an 10% wt./wt. intravenously injectable immune serum globulin solution, that is free from lipid enveloped viruses, has a low ionic strength, a pH of between 3.5-5.0, and a glycine concentration of about 0.2M, as recited by Claim 23. Gamimune N and the process for making it were not disclosed to the United States Patent Office.

All of this evidence establishes, at the very least, that it is not futile to allow Baxter to allege inequitable conduct.

## **2. Plaintiffs Will Suffer No Prejudice**

Baxter has not unduly delayed this request for leave to amend. Baxter diligently has analyzed the documents produced by plaintiffs and their deposition testimony. During this analysis, Baxter identified the Alonso Report and the 1993 PMT Project Status Report amongst the tens-of-thousands of pages produced by plaintiffs. Baxter has diligently sought and obtained deposition testimony of Dr. Alonso and the prosecuting attorneys to determine if Bayer had a reasonable basis for withholding this material information from the PTO. It does not. Baxter did not obtain any of this evidence until well past May 5, 2006, and in the case of Dr. Alonso's deposition testimony not until late September and early October. It was only after gathering all this information that Baxter determined it had the requisite evidentiary basis to make these allegations.

Plaintiffs will suffer no cognizable legal prejudice by the addition of the allegations. The facts relevant to Baxter's inequitable conduct allegations have always been in plaintiffs' possession. The witnesses who have relevant information are represented by plaintiffs' litigation counsel, so Talecris has unfettered access to them. To the extent these claims can be defended, Talecris and Bayer will have the full opportunity to do so. Therefore, they will suffer no legal prejudice from the proposed amendment.

### **3. Other Factors Favor Granting Baxter Leave To Amend**

In determining whether to grant leave to amend the trial court may consider other factors including bad faith or dilatory motive on the part of the moving party, repeated failure to cure deficiencies by amendments previously allowed, or futility of amendment. The diligence Baxter exercised in developing the requisite facts—through document review, analysis and depositions—establishes that Baxter has acted in good faith. And, as shown above, amendment would not be futile because the facts establish that material information in the possession of Bayer was withheld from the Patent Office. If it had been disclosed, the '191 Patent likely would not have been granted.

### **VI. Conclusion**

Baxter has exercised diligence in obtaining and analyzing discovery. This information demonstrates that Bayer failed to disclose data contrary to the very hypothesis upon which Dr. Alonso based his alleged invention, and selectively included outlier data that support his hypothesis. Likewise, Baxter has exercised diligence in ascertaining the facts necessary to allege that plaintiffs intentionally withheld material references and a material prior use. Much of the information required to make these allegations came after the deadline to amend pleadings had come and gone, and in some cases through deposition testimony of witnesses made available by Plaintiffs in late September or early October. Plaintiffs are not prejudiced by the addition of these allegations because they have control of all the relevant information and witnesses necessary to respond to them. Additionally, Baxter will require no further discovery, and by its motion Baxter simply seeks to conform the pleadings with the evidence it has obtained during discovery. Accordingly, to permit full consideration of the relevant issues on their merits as required by Rule 15 of the Federal Rules of Civil Procedure, Baxter respectfully requests that its



motion for leave to file an amended answer and counterclaim in the form submitted herewith be granted.

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# **EXHIBIT A**

Westlaw.

Not Reported in F.Supp.2d  
 Not Reported in F.Supp.2d, 2004 WL 1144054 (N.D.Ill.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 1

**H**Briefs and Other Related Documents

Douglas Press, Inc. v. Tabco Inc. N.D.Ill., 2004. Only the Westlaw citation is currently available.

United States District Court, N.D. Illinois, Eastern Division.

DOUGLAS PRESS, INC., an Illinois corporation,  
 Plaintiff,

v.

TABCO INC., a Delaware corporation, et al., Defendants.

No. 00 C 7338.

May 17, 2004.

Richard D. Harris, Herbert H. Finn, Greenberg Traurig, L.L.P., Chicago, IL, for Plaintiff.

Richard A. Zachar, Bruce A. Radke, Vedder, Price, Kaufman & Kammholz, P.C., Chicago, IL, for Defendants.

MEMORANDUM OPINION AND ORDER

ASHMAN, Magistrate J.

\*1 Pursuant to Federal Rule of Civil Procedure 15(a), Defendants Tabco Inc., Tabco Canada, and Specialty Print (collectively "Tabco") have filed a motion for leave to file an amended answer to the second amended complaint. Plaintiff Douglass Press, Inc. objects to this motion. The parties have consented to have this Court conduct any and all proceedings in this case, including the entry of final judgment. See 28 U.S.C. § 636(c); Local R. 73.1(a). For the following reasons, Tabco's motion is granted.

I. Background

In January of 2002, Douglas Press filed a second amended complaint alleging infringement of United States Patent No. 5,046,737 ("the '737 patent'"). Tabco timely answered the second amended complaint, denied infringement of the '737 patent, and alleged that the '737 patent was invalid. Discovery ensued, and Tabco asserts that it recently obtained corroborating evidence supporting a defense of inequitable conduct by Douglas Press. It filed its motion to amend its answer on March 31, 2004. Douglas Press

responds that the theory and facts behind the inequitable conduct defense, which include the testimony of a "disgruntled" former employee of Douglas Press, have been publically available to Tabco since approximately 1996. The employee's testimony was given to Tabco in 2002 during discovery of the instant case. Tabco responds that corroboration for the employee's testimony was found during depositions taken in late 2003. The deadline for the amendment of pleadings was March 11, 2003.

II. Discussion

Rule 15(a) provides that leave to amend responsive pleadings "shall be freely given when justice so requires." Nevertheless, the court may deny leave to amend where there exists "undue delay, bad faith, dilatory motive, undue prejudice to the opposing party, or when the amendment would be futile." Bethany Pharmacal Co. v. QVC, Inc., 241 F.2d 854, 861 (7th Cir.2001). The discretion to grant or deny a motion to amend remains with the trial court. Villa v. City of Chicago, 924 F.2d 629, 632 (7th Cir.1991). Douglas Press argues that the motion to amend should be denied because Tabco unduly delayed in seeking to amend its answer because it knew the facts behind the inequitable conduct allegations several years ago. It also argues that the proposed amendment will prejudice Douglas Press because the close of consolidated discovery May 31, 2004, and it will need to take discovery from third parties. Finally, Douglas Press argues that the inequitable conduct charge is a compulsory counterclaim, that having not been pled, has been waived.

The Court finds that Tabco did not unduly delay in seeking leave to amend its answer. As with fraud, allegations of inequitable conduct must be pled with particularity. Fed.R.Civ.P. 9(b); Heidelberg Harris, Inc. v. Mitsubishi Heavy Indus., Ltd., 95 C 0673, 1996 WL 680243, at \*2 (N.D.Ill. Nov. 21, 1996) (noting that inequitable conduct must be pled with the specificity requirements of Rule 9(b)). Tabco does not deny that it knew at a much earlier date of the former employee's testimony revealing that the inventor of the '737 patent and others at Douglas

Not Reported in F.Supp.2d  
 Not Reported in F Supp 2d, 2004 WL 1144054 (N.D.Ill.)  
 (Cite as: Not Reported in F.Supp.2d)

Page 2

Press were aware of relevant seal card games before the Douglas Press Bonus 300 game at issue was invented. This testimony was allegedly confirmed in depositions taken last year. Allegations of inequitable conduct are serious and we cannot fault Tabco for waiting for further evidence before filing such an affirmative defense, especially keeping in mind Rule 11 of the Federal Rules of Civil Procedure. Although Douglas Press disputes that such confirmation was necessary, it still asserts that the employee's testimony has been discredited. If the evidence were not reliable, it would be all the more reason for Tabco to wait to file its allegations.

\*2 Even if Tabco had unduly delayed in seeking leave to amend, we would still grant the motion because we also find that Douglas Press will not suffer undue prejudice if the proposed amendment is allowed. While the court will consider delay as one factor when deciding whether to grant a motion to amend, it must also find that the non-movant has suffered undue prejudice. King v. Cooke, 26 F.3d 720, 723 (7th Cir.1994); Stone Container Corp. v. Arkwright Mill. Ins. Co., No. 93 C 6626, 1996 WL 238904, at \*3-5 (N.D.Ill. May 2, 1996) (holding that even if the plaintiff did not provide a sufficient explanation for the delay, a complaint may be amended unless it burdens or causes undue prejudice to the defendant). Almost every amendment will result in some prejudice to the non-moving party, therefore the question is whether the prejudice is undue. Bell v. Am. Med. Ass'n, 00 C 0573, 2000 WL 1367946, at \*2 (N.D.Ill. Sept. 15, 2000).

Douglas Press' claims of prejudice center on the imminent close of discovery. It claims that it will have to take additional discovery from third parties which will take considerable time and resources. Tabco's affirmative defenses, however, include a claim that the '737 patent was not patentable over the prior art, including the seal card games at issue in the inequitable conduct defense. Tabco now seeks to add an allegation that Douglas Press knew of the prior art. Because the invalidity and inequitable conduct defenses are closely related, Douglas Press will not be unduly prejudiced by the amendment. See Bower v. Jones, 978 F.2d 1004, 1010 (7th Cir.1992) (finding no undue prejudice where claim was similar to those in original

complaint). If it needs to extend the discovery deadline, it will have to ask the court for additional time. Tabco could not in good conscience object to another extension, where the reason for the extended discovery was the amendment to its answer.

Finally, the Court finds that Tabco's claims of inequitable conduct do not constitute a compulsory counterclaim. Inequitable conduct is recognized as an affirmative defense. E.g., Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1376-77 (Fed.Cir.2004); Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1379-80 (Fed.Cir.2002). We will allow Tabco leave to amend its answer to add an affirmative defense of inequitable conduct. See cf. Mercexchange, LLC v. eBay, Inc., 271 F.Supp.2d 784, 789 (E.D.Va.2002).

### III. Conclusion

For the reasons above, the Court grants Defendants' Motion for Leave to File its Amended Answer.

N.D.Ill., 2004.

Douglas Press, Inc. v. Tabco Inc.

Not Reported in F.Supp.2d, 2004 WL 1144054 (N.D.Ill.)

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Not Reported in F.Supp.2d

Page 3

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Philip A. Rovner, hereby certify that on November 8, 2006, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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